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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,718	02/13/2002	Shubh D. Sharma	70025-02-US02	9717
5179	7590	01/03/2005		EXAMINER
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ALBUQUERQUE, NM 871256927			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 01/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/049,718	SHARMA ET AL.
	Examiner	Art Unit
	Jeffrey E. Russel	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5 and 7-63 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-5,9-17,19,21-25,34-36 and 41-63 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2,7,8,18,20,26-30,32,33,37 and 38 is/are rejected.
- 7) Claim(s) 31,39 and 40 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 March 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

1. Applicant's election of Group II and the species R₁-Bbb-Aaa-Ccc-R₂ in the reply filed on May 10, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1, 3-5, 9-17, 19, 21-25, 34-36, and 41-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 10, 2004.

2. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the composition" at claim 8, lines 1-2 and line 3.

3. Instant claims 2, 7, 8, 18, 20, 26-33, and 37-40 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/148,994 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose peptides in general in which the biological-function domain is co-extensive with at least a portion of the metal ion-binding domain, and does not disclose each of the generic formulas recited in instant claim 18, and in particular does not disclose the formula corresponding to the elected species R₁-Bbb-Aaa-Ccc-R₂. Accordingly, Sharma (U.S. Patent No. 5,891,419), the Fabris et al article (Inorganic Chemistry, Vol. 38, pages 1322-1325), and the Giblin et al article (PNAS, Vol. 95, pages 12814-12818) are available as prior art against these claims under 35 U.S.C. 102(b), and the Shi et al abstract (Abstracts Of Papers, American Chemical Society,

218th ACS National Meeting, Part 1, Abstract MEDI 257) is available as prior art against these claims under 35 U.S.C. 102(a).

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 2, 8, 18, 26-30, 32, 33, 37, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fabris et al article (Inorganic Chemistry, Vol. 38, pages 1322-1325). The Fabris et al article teaches zinc-finger peptides comprising the sequence Pro-Tyr-Lys-Cys, in which the Pro corresponds to Applicants' R₁, the Tyr corresponds to Applicants' Bbb, the Lys corresponds to Applicants' Aaa, the Cys corresponds to Applicants' Ccc, and the remainder of the zinc finger peptides comprise Phe, an amino acid with an aromatic sidechain, which remainder corresponds to Applicants' R₂. The zinc-finger peptides are amidated at their C-terminus. The zinc-finger peptides complex with and are conformationally restrained by zinc. See, e.g., Figure 1. With respect to instant claim 27, the Pro residue in the zinc-finger peptides of the Fabris et al article comprises a -(CH₂)₃- group in its sidechain, which is a linear alkyl chain. With respect to instant claim 30, the Tyr residue in the zinc finger peptides of the Fabris et al article is a derivative, analog, and/or homolog of the specific residues recited in Applicants' claim because it comprises an aromatic sidechain. Note that Applicants' specification does not define "derivative", "analog", or "homolog" so as to exclude this interpretation. With respect to instant claim 37, the remainder of the zinc finger peptides of the Fabris et al article is a derivative, analog, and/or homolog of the specific residues recited in Applicants' claim because it comprises a Phe residue. Note that Applicants' specification does not define "derivative", "analog", or "homolog" so as to exclude this interpretation. In view of the similarity in structure

and function between the zinc-finger peptides of the Fabris et al article and Applicants' claimed peptides, the zinc-finger peptides are deemed inherently to have a determined biological-function domain, to have a biological-function domain which is co-extensive with at least a portion of a metal ion-binding domain, and to be substantially more specific for one or more melanocortin receptors when in the complexed state in comparison to the uncomplexed state, to the same extent claimed by Applicants. In view of the similarity in structure between the zinc-finger peptides of the Fabris et al article and Applicants' claimed peptides, the Lys residue and the Tyr residue of the zinc-finger peptides of the Fabris et al article are deemed inherently to provide an N for metal ion complexation to the same extent claimed by Applicants. Note that although the Lys and Tyr residues do not provide an N for metal ion complexation in the specific examples illustrated by Figure 1 of the Fabris et al article, this does not mean that there are no metals or conditions under which the Lys and/or Tyr residues in the zinc-finger peptides of the Fabris et al article will not provide an N for metal ion complexation. Note that Applicants' claims 29 and 32 do not specify any particular metals or conditions under which metal ion complexation must occur. Sufficient evidence of similarity is deemed to be present between the zinc-finger peptides of the Fabris et al article and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than the zinc-finger peptides of the Fabris et al article.

6. Claims 2, 7, 8, 18, 20, 27-30, 32, 33, 37, and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by the Shi et al abstract (Abstracts Of Papers, American Chemical Society, 218th ACS National Meeting, Part 1, Abstract MEDI 257). The Shi et al abstract teaches an

acetylated and amidated peptide, His-Phe-Arg-Cys-Trp, complexed with rhenium, and which is highly specific for MCR-1.

7. Claims 2, 7, 8, 18, 20, 26-29, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by the Giblin et al article (PNAS, Vol. 95, pages 12814-12818). The Giblin et al article teaches the peptides NAc-Cys-Glu-His-D-Phe-Arg-Trp-Cys-Lys-Pro-Val-NH₂ and NAc-Cys-Cys-Glu-His-D-Phe-Arg-Trp-Cys-Lys-Pro-Val-NH₂, which correspond to Applicants' peptide of the formula R₁-Fff-Aaa-Ggg-Ccc-R₅, where NAc-Cys-Glu-His and NAc-Cys-Cys-Glu-His, respectively, are R₁; D-Phe is Fff; Arg is Aaa; Trp is Ggg; Cys is Ccc; and Lys-Pro-Val-NH₂ is R₅ which is a substituted amide or which comprises an L- or D-amino acid. The peptides are complexed and cyclized with Re or Tc. The complexed peptides are specific for α-MSH receptors. See, e.g., the Abstract; page 12815, column 1, first full paragraph; and Figure 1. In view of the similarity in structure and function between the peptides of the Giblin et al abstract and Applicants' claimed peptides, the peptides of the Giblin et al abstract are deemed inherently to have a determined biological-function domain, to have a biological-function domain which is co-extensive with at least a portion of a metal ion-binding domain, and to be substantially more specific for one or more melanocortin receptors when in the complexed state in comparison to the uncomplexed state, to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the peptides of the Giblin et al abstract and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than the peptides of the Giblin et al abstract.

8. Applicant's arguments filed December 2, 2004 have been fully considered but they are not persuasive.

The terminal disclaimer filed December 2, 2004 has been approved.

The examiner maintains his position that the instant claims are not entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/148,994. It should first be noted that whether or not a claim is entitled to priority under 35 U.S.C. 119(e) is a question of written description, not enablement. See, e.g., MPEP 2163.03(III). Secondly, it should be noted that a claim is entitled to the benefit of the filing date of a priority application only if the claim is limited solely to subject matter disclosed in the priority application. See MPEP 201.11(VI). With respect to Applicants' particular arguments, Applicants contend that the disclosure at page 16, first paragraph, and in particular the description of variables R₁ and R₂, constitutes "enablement" (sic - written descriptive support) for the claim limitation that the biological-function domain is co-extensive with at least a portion of the metal ion-binding domain. However, this disclosure in the provisional application is limited to metallopeptides having the structure of the recited formula, whereas instant claim 2 is not limited to such a formula. Instant claim 2 is broader in scope than the disclosure at 16, first paragraph, of the provisional application, and disclosure of a species in a parent application does not provide written descriptive support for a genus claimed in a child application. Further, it appears that the reverse turn structure disclosed in the provisional application is only a species of the metal ion-binding domain claimed in the instant application (unless Applicants are implicitly stating that the metal ion-binding domains of the instant claims are limited to reverse turn structures). Again, a species does not provide written descriptive support for a genus. With respect to the provisional application's disclosure of compounds PL-1144, PL-1145, and PL-837, three species

of compounds do not provide written descriptive support for the uncountable number of compounds embraced by the elected species R₁-Bbb-Aaa-Ccc-R₂.

The rejection based upon Sharma (U.S. Patent No. 5,891,418) is withdrawn because, as argued by Applicants, the instant claimed peptides do not embrace the peptides of Examples 44 and 46 of Sharma.

The rejection based upon the Fabris et al article (Inorganic Chemistry, Vol. 38, pages 1322-1325) is maintained. As noted above, the instant claims are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the parent provisional application. Further, while Applicants have argued that the Fabris et al article is not available as prior art under 35 U.S.C. 102(b), Applicants failed to provide any reasons why the Fabris et al article should not then be applied under 35 U.S.C. 102(a). The examiner agrees that claims 7 and 20, as currently amended, are no longer taught or suggested by the Fabris et al article.

The rejection over the Shi et al abstract (Abstracts Of Papers, American Chemical Society, 218th ACS National Meeting, Part 1, Abstract MEDI 257) is maintained. For the reasons set forth above, the Shi et al abstract is deemed to be available as prior art under 35 U.S.C. 102(a). Applicants argue that the draft poster presentation underlying the Shi et al abstract was included in the provisional application as Figure 5. However, in determining whether or not Applicants are entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the provisional application, the issue is whether or not the claimed subject matter is disclosed in the provisional application. The issue is not whether the subject matter of the prior art reference is disclosed in the provisional application. Applicants contend that because four of the six named authors of the Shi et al abstract are named inventors of the instant application, the Shi et

al abstract is not “by others” under 35 U.S.C. 102(a). This argument is incorrect. Any difference between authorship and inventorship satisfies the statutory requirement that a reference applied under 35 U.S.C. 102(a) be “by others”. See MPEP 2136.04. Applicants’ attorney’s arguments are not a substitute for showings that are required to be made under 37 CFR 1.131 or 1.132.

The rejection based upon the Giblin et al article (PNAS, Vol. 95, pages 12814-12818) is maintained. As noted above, the instant claims are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of the parent provisional application. Further, while Applicants have argued that the Giblin et al article is not available as prior art under 35 U.S.C. 102(b), Applicants failed to provide any reasons why the Giblin et al article should not then be applied under 35 U.S.C. 102(a). As set forth in the rejection, the peptides of the Giblin et al article are deemed to anticipate Applicants’ claimed peptides. The concept of “teaching away” concerns only obviousness rejections and is irrelevant to anticipation analyses. Finally, peptides of the elected formula are not limited to a single cysteine residue. Additional cysteine residues can be present as part of R₁.

9. Claims 31, 39, and 40, limited to the elected species, are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
December 27, 2004